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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/588,924	06/06/2000	Roger P. Jackson	00,063	9408

7590 03/06/2002

John C McMahon
PO Box 30069
Kansas City, MO 64112

EXAMINER
DAVIS, DANIEL J

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 03/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/588,924	Applicant(s) JACKSON, ROGER P.	
	Examiner Daniel J Davis	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *June 6, 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:

   - Examiner recommends replacing "it foreseen" for "it is foreseen" (Page 9, lines 2-3).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1(c) recites the limitation "secured cross section". There is insufficient antecedent basis for this limitation in the claim. Examiner recommends changing "secured" to "second".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

3. Claims 1-3 and 9-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Mellinger et al. (US 6,302,888 B1).

4. Regarding claim 1, Mellinger discloses a "closure [Fig. 5] for use in conjunction with a medical implant having an inward threaded surface [50]". Examiner treats the closure comprising both the set screw shown alone in Fig. 10, and the closure member 16 (Fig. 5) for claims 1-3. The closure body (Fig. 5) has an outward threaded surface 50 that mates with the implant. The driving head 74 has a cross section perpendicular to the axis of rotation (Fig. 5). The removal heads 80 (Fig. 10) have a cross section perpendicular to the axis of rotation and are different from the driving head 74. (The cross section shapes and sizes are different.)

5. Please note that Examiner treats the prongs 80 as removal heads 80. There are multiple removal heads 80.

6. Regarding claim 2, the driving head 74 is joined to the closure body by a breakaway region 76 (Fig. 5). The breakaway region 76 breaks away when a predetermined force is applied to the driving head 74 (Col. 5, lines 9-11).

7. Regarding claim 3, the removal heads 80 are positioned between the closure body and the driving head 74. The removal heads 80 must be situated outside of the closure member 16.

8. Regarding claim 4, the driving head 74 cross section has a polyhedral shape that is different from the cross section of the removal heads 80.

9. Regarding claim 9, Mellinger discloses a closure having a cylindrical shaped closure body (Fig. 10) with threads 70 on its outer surface and is received between the arms of a medical implant. For claims 9-11 and 13, examiner treats the apparatus of Fig. 10 alone as the closure.

10. The driving head 74 is attached to the closure body and has a gripable outer surface 74.

11. The removal heads 80 are attached to the closure body 30 and have a gripable outer surface. The removal heads 80 have a surface configured differently from that of the driving head 74 (its size is smaller and its shape is different), which prevents the insertion tool from inadvertently mating with both the driving head 74 and the removal heads 80.

12. Regarding the use of the closure in an "open headed medical implant having a pair of interiorly threaded arms for receiving the closure", the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

13. Regarding claim 10, the driving head 74 is attached to the closure body at a breakaway region 76 (Fig. 10). The driving head 74 breaks away from the closure body when a preselected torque is applied to it (Col. 5, lines 9-11).

14. Regarding claim 11, the driving head 74 and the removal heads80 have cross sections that are different shapes.

15. Regarding claim 12, the driving head 74 has a cross section that is larger than one of the removal heads 80 (Fig. 10). (The cross section of the removal heads 80 only includes one head 80 even though there are multiple heads.)

16. Regarding claim 13, the driving head 74 and one of the removal heads 80 each have a different number of faces that form a polyhedral cross section.

17. Claims 1, 2, and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Gournay et al. (US 6,193,719 B1).

18. Regarding claim 1, Gournay discloses a "closure [Fig. 1] for use in conjunction with a medical implant having an inward threaded surface". The closure body 3 has an outwardly threaded surface 5 that mates with an implant (Fig. 11). The driving head 6 has a cross section perpendicular to the axis of rotation. The removal head 3,7 has a cross section perpendicular to the axis of rotation and different from the driving head 6.

19. Regarding claim 2, the driving head 6 is joined to the closure body by a breakaway region 4 (Fig. 1). The breakaway region 4 breaks away when a predetermined force is applied to the driving head 6 (Col. 1, lines 47-51 and Col. 2, lines 34-35).

20. Regarding claim 4, the driving head 6 and the removal head 3,7 have different shapes, which prevent the installation tool from inadvertently gripping the removal head 6. Gournay teaches that the shape of either the driving head or the removal head may be of any shape (Col. 4, lines 46-51). This implies that the shape of the driving head and the cross section shapes may be different polyhedral shapes.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cortel (US 5,154,719) in view of Gournay.

22. Regarding claim 5, Cortel discloses a system comprising an open headed implant having interiorly threaded 9 arms 6 in conjunction with a closure 10. The closure 10 has a cylindrical shaped body (Fig. 1) with a driving head 8 and a removal head 8 (the heads are one in the same). Cortel fails to disclose that the driving head 8 has a different cross section from the removal head 8. Cortel also fails to disclose a driving head that breaks away at a predetermined torque.

23. Gournay teaches a closure (Fig. 1) having a driving head 6 with a cross section different from that of the removal head 7,3. The driving head breaks away at a

predetermined torque, (Col. 1, lines 46-51) which improves clamping torque precision (Col. 1, lines 52-60).

24. Therefore, it would have been obvious to one of ordinary skill in the art to modify the closure 10 (Fig. 1) disclosed by Cortel by adding the breakaway driving head 6 as taught by Gournay to improve clamping torque precision.

25. Regarding claim 6, the driving head taught by Gournay has a driving head 6 that is connected to the closure body (Fig. 1) by a breakaway region 4. The driving head 6 breaks away at a predetermined torque (Col. 1, lines 46-51).

26. Regarding claim 7, the removal head 7,3 is centered between the closure body (Fig. 1) and driving head 6. An imaginary line can be drawn halfway between the breakaway region 4, and the bottom of the closure body/removal head 3,7. The upper half constitutes the removal head, and the lower half constitutes the body.

27. Regarding claim 8, Gournay teaches a driving head 6 having a cross section having a different polyhedral shape from that of the removal head. Cortel discloses a hexagonal cross section. Gournay teaches that the shape of either the driving head or the removal head may be of any shape (Col. 4, lines 46-51). This implies that the shape of the driving head and the cross section shapes may be different polyhedral shapes.

Conclusion

28. The following references disclose breakaway heads that are attached to screws or nuts that screw on: Devlin et al. (US 3,742,583), Williamson (US 4,408,936), Sato (US 4,729,703.), Matuschek (US 4,518,295), Reed (US 4,662,806), Reed (US 5,499,892), Allsop (US 3,370,341), Reiland (US 3,812,757), Mellinger (US 6,302,888 B1) and Yamada (US 4,502,825).

29. Reiland, Allsop, Yamada and Devlin disclose both a driving head and a removal head attached to a screw.

30. Mellinger '888 discloses a breakable head for a closure in conjunction with a medical implant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel J Davis whose telephone number is (703) 305-1232. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-7721 for regular communications and (703) 746-7721 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

DJD
February 25, 2002

DAVID O. REIP
PRIMARY EXAMINER